

**KENTUCKY**  
**CONTROLLED SUBSTANCES**  
**ASSOCIATED ADMINISTRATIVE REGULATIONS**



**CABINET FOR HEALTH AND FAMILY SERVICES**  
**OFFICE OF THE INSPECTOR GENERAL**  
**DRUG ENFORCEMENT AND PROFESSIONAL PRACTICES BRANCH**  
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**KRS Chapter 218A**

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**KENTUCKY ADMINISTRATIVE REGULATIONS**  
**TITLE 902**  
**CHAPTER 55**  
**CONTROLLED SUBSTANCES**

**902 KAR 55:010. Licensing of manufacturers and wholesalers.**

RELATES TO: KRS 218A.150 (1), 218A.160, 218A.170, 218A.200, 21 C.F.R. 210.1-210.3, 211.1-211.208, 1301.01-1301.93, 1304.01-1304.33

STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 211.090, 218A.150 (1), 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.150, 218A.160 and 218A.170 authorize the Cabinet for Health Services to license manufacturers and wholesalers of controlled substances. This administrative regulation establishes uniform requirements for the licensing of manufacturers and wholesalers.

**Section 1. Definitions.**

- (1) "Health care entity" means any organization, or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care.
- (2) "Manufacturer" means a person engaged in the commercial manufacture of a controlled substance.
- (3) "Wholesale distribution" means distribution of a controlled substance to a person other than a consumer or a patient, and shall not include:
  - (a) An intracompany sale; or
  - (b) A distribution by:
    1. A charitable organization that meets the criteria established in 26 USC 501(c)(3) to a nonprofit affiliate of the organization to the extent permitted by law;
    2. A hospital or health care entity which is a member of a group-purchasing organization to other hospitals or health care entities that are members of the organization; or
    3. A pharmacy that is exempt pursuant to 902 KAR 55:060.
- (4) "Wholesaler" means a person who is engaged in the wholesale distribution of a controlled substance, including:
  - (a) Own-label distributor;
  - (b) Private-label distributor;
  - (c) Jobber;
  - (d) Broker;
  - (e) Warehouse, including a manufacturers' or distributors' warehouse, chain drug warehouse, or wholesale drug warehouse;
  - (f) Independent wholesale drug trader; and
  - (g) Pharmacy that conducts wholesale distributions.

**Section 2. License Required and Exceptions.**

- (1) A separate license shall be required for each location from which a manufacturer or wholesaler makes a wholesale distribution of a controlled substance into the Commonwealth.

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- (2) If a location has more than one (1) registration with the Drug Enforcement Administration, each registrant that distributes in the Commonwealth shall obtain a separate license.
- (3) A license to distribute controlled substances shall not be transferred or assigned.
- (4) A license shall not be required for an agent or employee of a licensee if the agent or employee is acting in the usual course of business or employment.

### **Section 3. Application for License or Renewal.**

- (1) An application for a manufacturer's or wholesaler's license shall be submitted to the Cabinet for Health Services on "Application for New License as Manufacturer or Wholesaler of Controlled Substances", DCB-10 form, and include the following information:
  - (a) The name, business address and telephone number of the prospective licensee;
  - (b) All trade or business names used by the licensee;
  - (c) Name, address, and telephone number of each contact person for controlled substance handling, storage, and recordkeeping;
- (2) An application for a manufacturer's or wholesaler's license shall include the following information about the ownership of the business:
  - (a) The type of ownership of operation;
  - (b) If an individual or sole proprietorship, the full name of the individual or proprietor and the name of the business entity;
  - (c) If a partnership, the name and address of each partner and the name of the partnership;
  - (d) If a limited liability company, the name and address of each manager and member; and
  - (e) If a corporation, the name and title of each corporate officer and director, the corporate names, and the names of the state of incorporation.
- (3) A description of the business, the physical facilities, and the type security provided.
- (4) A change in the information required by subsection (1), (2), or (3) shall be submitted to the cabinet:
  - (a) Within thirty (30) days from the date of the change, or at the time of license renewal, whichever occurs first; and
  - (b) On a "License Update Manufacturer or Wholesaler of Controlled Substances", DCB-11 or an "Application for Renewal License as Manufacturer or Wholesaler of Controlled Substances", DCB-12.

### **Section 4. Qualifications for License or Renewal.**

- (1) The cabinet shall consider the following factors in reviewing the qualifications of an applicant to engage in the manufacture or wholesale distribution of controlled substances:
  - (a) A conviction of the applicant or its managing officers under any federal, state, or local law relating to controlled substances;
  - (b) A felony conviction of the applicant or its managing officers;
  - (c) An applicant's history with state or federal regulatory agencies as related to the manufacture or distribution of controlled substances;
  - (d) The furnishing of false or fraudulent information in connection with an application for a license from a federal, state or local government agency;
  - (e) Suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of controlled substances;
  - (f) Compliance with licensing requirements under previously granted licenses, if any;

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- (g) Compliance with requirements to maintain or make available to the cabinet or to federal, state, or local law enforcement officials those records required by KRS 218A.200;
  - (h) The criteria listed in KRS 218A.160; and
  - (i) Violations of applicable federal law, rule or regulation or state law, or administrative regulation governing a controlled substance that relates to Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs in 21 CFR 210.1 to 210.3 or Current Good Manufacturing Practice for Finished Pharmaceuticals in 21 CFR 211.1 to 211.208, adopted by the U.S. Food and Drug Administration.
- (2) A license shall be renewed if the cabinet finds that the applicant:
- (a) Qualifies for a license pursuant to subsection (1) of this section;
  - (b) Complies with Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances 21 CFR 1301.01 through 1301.93, adopted by the Drug Enforcement Administration;
  - (c) Complies with Records and Reports of Registrants 21 CFR 1304.01 through 1304.33, adopted by the U.S. Drug Enforcement Administration;
  - (d) Complies with KRS 315.036 and 201 KAR 2:105; and
  - (e) Complies with KRS 218A.200.
- (3) A manufacturer or wholesaler not located within the Commonwealth of Kentucky may obtain a license or license renewal on the basis of reciprocity if:
- (a) The out-of-state manufacturer or wholesaler possesses a valid license granted by another state and the legal standards for licensure in the other state are no less stringent than the standards established by this administrative regulation;
  - (b) The out-of-state manufacturer or wholesaler is currently registered with the U.S. Drug Enforcement Administration; and
  - (c) The state in which it is licensed extends reciprocity to manufacturers and distributors licensed by Kentucky.
- (4) All administrative hearings shall be conducted in accordance with 902 KAR 1:400.

### **Section 5. License Fees; Renewals.**

- (1) An application for a license under the provisions of this administrative regulation shall be submitted to the Cabinet for Health Services on an "Application for New License as Manufacturer or Wholesaler of Controlled Substances" DCB-10 form and shall be accompanied by a license fee of \$240.
- (2) An application to renew a license shall be submitted to the Cabinet for Health Services on an "Application for Renewal License as Manufacturer or Wholesaler of Controlled Substances", DCB-12 form, and shall be accompanied by a renewal fee of \$175.

### **Section 6. Recordkeeping.**

- (1) Records shall be maintained in accordance with KRS 218A.200 and with 21 CFR 1304.01 to 1304.33, adopted by the U.S. Drug Enforcement Administration.
- (2) Records or copies of records that relate to distributions within the Commonwealth shall be made available to the cabinet upon request.

### **Section 7. License Termination, Lapse, Suspension or Revocation.**

- (1) A license issued pursuant to this administrative regulation shall be suspended or revoked for cause.

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- (2) A license shall terminate if the licensee dies or ceases legal existence.
- (3) A license shall lapse if the renewal application and renewal fee have not been filed with the cabinet prior to June 30 of each year.
- (4) A lapsed license shall be void and an application for a new license shall be required.
- (5) All administrative hearings shall be conducted in accordance with 902 KAR 1:400.

### **Section 8. Incorporation by Reference.**

- (1) The following material is incorporated by reference:
  - (a) "Application for New License as Manufacturer or Wholesaler of Controlled Substances (8/98)", DCB-10;
  - (b) "License Update Manufacturer or Wholesaler of Controlled Substances (8/98)", DCB-11;
  - (c) "Application for Renewal License as Manufacturer or Wholesaler of Controlled Substances (8/98)", DCB-12.
- (2) This material may be inspected, copied, or obtained at the Cabinet for Health Services, Department for Public Health, Drug Control and Professional Practices, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. - 4:30 p.m.  
(Recodified from 901 KAR 1:010, 4-14-82; Am. 8 Ky.R. 1181; 1601; eff. 6-25-82; 11 Ky.R. 1673; eff. 6-4-85; 14 Ky.R. 2084; eff. 6-22-88; 17 Ky.R. 136; eff. 9-13-90; 22 Ky.R. 2480; 8-1-96; 25 Ky.R. 625; 1628; eff. 1-19-99.)

### **902 KAR 55:015. Schedule I substances.**

RELATES TO: KRS 218A.010-218A.050, 21 C.F.R. 1308.11

STATUTORY AUTHORITY: KRS 194A.050, 218A.020, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to protect the health of the individual citizens of the commonwealth, to operate programs and fulfill the cabinet's responsibilities, or to implement federal law. KRS 218A.250 requires the cabinet to promulgate administrative regulations to carry out the provisions of KRS Chapter 218A. KRS 218A.020 authorizes the Cabinet for Health and Family Services to promulgate administrative regulations in order to add substances to or delete or reschedule substances enumerated in KRS Chapter 218A. This administrative regulation establishes Schedule I drugs. This administrative regulation differs from the federal regulation, 21 C.F.R. 1308.11, because it designates substances that are substantially similar to synthetic cannabinoids as Schedule I controlled substances.

**Section 1. Opiates.** The Cabinet for Health and Family Services hereby designates as Schedule I controlled substances, in addition to those specified by KRS 218A.050, any of the following opiates, including their isomers, optical isomers, esters, ethers, salts, salts of isomers, esters, and ethers, unless specifically excepted, if the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (1) Alphacetylmethadol (except Levo-alphacetylmethadol LAAM);
- (2) Acetyl-alpha-methylfentanyl, N-1-(1-methyl-2-phenethyl)-4-piperidinyl -N- phenylacetamide;
- (3) Alpha-methylfentanyl, N-1-(alpha-methyl-beta-phenyl) ethyl-4-piperidyl propionanilide, 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

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- (4) Alpha-methylthiofentanyl, N-1-methyl-2-(2-thienyl) ethyl-4-piperidiny-N- phenylpropanamide;
- (5) Benzylfentanyl, N-1-benzyl-4-piperidyl-N-phenylpro-panamide;
- (6) Beta-hydroxyfentanyl, N-1-(2-hydroxy-2-phenethyl)-4-piperidiny-N-phenylpropanamide;
- (7) Beta-hydroxy-3-methylfentanyl,N-1-(2-hydroxy-2phenethyl)-3-methyl-4-piperidiny-N-phenylpropanamide;
- (8) Difenoxin;
- (9) 3-Methylfentanyl, N-3-methyl-1-(2-phenylethyl)-4-piperidyl-N-phenylpropanamide;
- (10) 3-methylthiofentanyl N-3-methyl-1-(2-thienyl) ethyl-4-piperidiny-N-phenylpropanamide;
- (11) 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP);
- (12) Para-fluorofentanyl, (N-(4-fluorophenyl)-N-1-(2-phenethyl)-4-piperidinypropanamide;
- (13) 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP);
- (14) Thenylfentanyl, N-1-(2-thienyl) methyl-4-piperidyl-N-phenyl-propanamide;
- (15) Thiofentanyl N-phenyl-N-1-(2-thienyl)ethyl-4-piperidinypropan-amide; and
- (16) Tilidine.

### Section 2. Opium Derivatives.

The Cabinet for Human Resources hereby designates as Schedule I controlled substances, in addition to those specified by KRS 218A.050, any of the following opium derivatives, their salts, optical isomers, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, optical isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Drotebanol; and
- (2) Etorphine (except hydrochloride salt).

### Section 3. Hallucinogenic Substances.

The Cabinet for Human Resources hereby designates as Schedule I controlled substances, in addition to those specified by KRS 218A.050, any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation :

- (1) alpha-ethyltryptamine (alpha-ethyl-1H-indole-3-ethanamine,3-(2-aminobutyl)indole);
- (2)4-bromo-2,5-dimethoxy-amphetamine(4-bromo-2,5-DMA,4-bromo-2,5-dimethoxy-alpha-methylphenethylamine);
- (3) 2,5-dimethoxyamphetamine (2,5-DMA);
- (4) 2,5-dimethoxy-4-ethylamphetamine (DOET);
- (5) Ethylamine analog of phencyclidine (N-ethyl-1-phenylcy-clohexylamine, cyclohexamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, PCE);
- (6) 3,4-methylenedioxymethamphetamine (MDMA);
- (7) 4-methoxyamphetamine (PMA, 4-methoxy-alphamethylphen-ethylamine, paramethoxyamphetamine);
- (8) 3,4-methylenedioxy-N-ethylamphetamine (N-ethyl-alpha-methyl-3,4(methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA);
- (9)N-hydroxy-3,4-methylenedioxyamphetamine(N-hydroxy-alpha-methyl 3,4(methylenedioxy)phenethylamine, N-hydroxy MDA);
- (10) Parahexyl (Synhexyl, 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo b,d pyran);

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- (11) Pyrrolidine analog of phencyclidine (1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP);
- (12) Thiophene analog of phencyclidine (1-(1-(2-thienyl)cyclo-hexyl)piperidine, TCP, TPCP); and
- (13) 1-1-(2-thienyl) cyclohexylpyrrolidine (TCPy).
- (14) 2-(2,5-dimethoxyphenyl)-N-{(2-methoxyphenyl)methyl}ethanamine (2,5H-NBOMe);
- (15) 2-(4-iodo-2,5-dimethoxyphenyl)-N-{(2-methoxyphenyl)methyl}ethanamine (2,5I-NBOMe);
- (16) 2-(4-bromo-2,5-dimethoxyphenyl)-N-{(2-methoxyphenyl)methyl}ethanamine (2,5B-NBOMe); and
- (17) 2-(4-chloro-2,5-dimethoxyphenyl)-N-{(2-methoxyphenyl)methyl}ethanamine (2,5C-NBOMe).

### Section 4. Depressants.

The Cabinet for Human Resources hereby designates as Schedule I controlled substances, in addition to those specified by KRS 218A.050, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Mecloqualone; and
- (2) Methaqualone.

### Section 5. Stimulants.

The Cabinet for Human Resources hereby designates as Schedule I controlled substances, in addition to those specified by KRS 218A.050, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Aminorex (aminoxaphen, 2-amino-5-phenyl-2-oxazoline, 4,5-dihydro-5-phenyl-2-oxazolamine);
- (2) Cathinone (2-amino-1-phenyl-1-propanone, alpha-aminopro-piophenone, 2-aminopropiophenone, and norephedrone;
- (3) (±) cis-4-methylaminorex ((±) cis-4,5-dihydro-4methyl-5-phenyl-2-oxazolamine);
- (4) N,N-dimethylamphetamine (N,N-alpha-trimethyl-benzeneetha-namine, N,N,alpha-trimethylphenethylamine), its salts, optical isomers and salts of optical isomers;
- (5) N-ethylamphetamine;
- (6) Fenethylamine; and
- (7) Methcathinone (2-(methylamino)-propionophenone, alpha (methylamino)-propionophenone, alpha (methylamino)-propionophenone, 2-(methylamino)-1-phenylpropan-1-one, alpha-N-methylaminopropionophenone, monomethylpropion, ephedrone, N-methylcathinone, methylcathinone, AL-464, AL-422, AL-463 and UR1431) its salts, optical isomers and salts of optical isomers.
- (8) Paramethoxymethamphetamine (PMMA); and
- (9) Paramethoxyamphetamine (PMA).

### Section 6. Synthetic Cannabinoids.

The Cabinet for Health and Family Services hereby designates as Schedule I controlled substances, in addition to those specified by KRS 218A.050, any substance, compound, mixture, or preparation which contains any quantity of any synthetic cannabinoid and is not an FDA approved drug, including the following:



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- (1) (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144);
  - (2) (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11);
  - (3) 1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201);
  - (4) 1-naphthalenyl(1-pentyl-1H-indazol-3-yl)-methanone (THJ-018);
  - (5) (1-(5-fluoropentyl)-1H-benzimidazol-2-yl)(naphthalen-1-yl)methanone (AM2201-benzimidazole analog, FUBIMINA);
  - (6) Indole-3-carboxylate esters: Any compound containing a 1H-indole-3-carboxylate ester structure with the ester oxygen bearing a naphthyl, quinolinyl, isoquinolinyl, or adamantyl group and substitution at the one (1) position of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, benzyl, N-methyl-2-piperidinylmethyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not further substituted on the naphthyl, quinolinyl, isoquinolinyl, adamantyl, or benzyl groups to any extent. Examples of this structural class include PB-22 and 5F-PB-22; and
  - (7) Indazole-3-carboxamides: Any compound containing a 1H-indazole-3-carboxamide structure with substitution at the nitrogen of the carboxamide by a naphthyl, quinolinyl, isoquinolinyl, adamantyl, or 1-amino-1-oxoalkan-2-yl group and substitution at the one (1) position of the indazole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, benzyl, N-methyl-2-piperidinylmethyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indazole ring to any extent and whether or not further substituted on the naphthyl, quinolinyl, isoquinolinyl, adamantyl, 1-amino-oxoalkan-2-yl, or benzyl groups to any extent. Examples of this structural class include AB-FUBINACA and AB-CHMINACA.
- 901 KAR 1:015, 4-14-1982; Am. 11 Ky.R. 1674; eff. 6-4-1985; 12 Ky.R. 266; eff. 9-10-1985; 1175; eff. 2-4-1986; 13 Ky.R. 1944; eff. 6-9-1987; 15 Ky.R. 863; eff. 11-4-1988; 20 Ky.R. 659; eff. 10-21-1993; 39 Ky.R. 1789; 2032; eff. 5-3-2013; 42 Ky.R. 1972; eff. 3-4-2016.)

### **902 KAR 55:020. Schedule II substances.**

RELATES TO: KRS 218A.010-218A.030, 218A.060-218A.070, 21 C.F.R. 1308.12

STATUTORY AUTHORITY: KRS 218A.020(1), (3)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(1) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations in order to add, delete, or reschedule substances enumerated in KRS Chapter 218A. KRS 218A.020(3) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations to control substances controlled under federal law. This administrative regulation designates Schedule II controlled substances.

#### **Section 1. Substances, Vegetable Origin or Chemical Synthesis.**

The Cabinet for Health and Family Services designates as a Schedule II controlled substance any material, compound, mixture, or preparation that contains any quantity of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

- (1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;
- (2) Any salt, compound, isomer, derivative, or preparation thereof that is chemically equivalent or identical with any of the substances referred to in subsection (1) of this section, except for the

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- isoquinoline alkaloids of opium;
- (3) Opium poppy and poppy straw; and
  - (4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, including cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives, and any salt, compound, isomer, derivative, or preparation thereof that is chemically equivalent or identical with any of these substances, except for decocainized coca leaves or extractions of coca leaves that do not contain cocaine, ecgonine, or ioflupane.

### **Section 2. Opium and Derivatives.**

The Cabinet for Health and Family Services designates as a Schedule II controlled substance, in addition to those specified by KRS 218A.070, opium and opiates, and a salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts, including the following:

- (1) Raw opium;
- (2) Opium extracts;
- (3) Opium fluid;
- (4) Powdered opium;
- (5) Granulated opium;
- (6) Tincture of opium;
- (7) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form that contains the phenanthrene alkaloids of the opium poppy);
- (8) Codeine;
- (9) Dihydroetorphine;
- (10) Ethylmorphine;
- (11) Etorphine hydrochloride;
- (12) Hydrocodone (dihydrocodeinone), including all hydrocodone combination products;
- (13) Hydromorphone;
- (14) Metopon;
- (15) Morphine;
- (16) Oripavine;
- (17) Oxycodone;
- (18) Oxymorphone; and
- (19) Thebaine.

### **Section 3. Opiates.**

The Cabinet for Health and Family Services designates as a Schedule II controlled substance, in addition to those specified by KRS 218A.070, the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers if the existence of the isomers, esters, ethers, or salts is possible within the specific chemical designation, excluding dextrorphan and levopropoxyphene:

- (1) Alfentanil;
- (2) Alphaprodine;
- (3) Anileridine;
- (4) Bezitramide;
- (5) Bulk dextropropoxyphene, in nondosage forms;

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- (6) Carfentanil;
- (7) Dihydrocodeine;
- (8) Diphenoxylate;
- (9) Fentanyl;
- (10) Isomethadone;
- (11) Levo-alpha-acetylmethadol (some other names include levo-alpha-acetylmethadol, levomethadyl acetate, LAAM);
- (12) Levomethorphan;
- (13) Levorphanol;
- (14) Metazocine;
- (15) Methadone;
- (16) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane;
- (17) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;
- (18) Pethidine (meperidine);
- (19) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
- (20) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;
- (21) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
- (22) Phenazocine;
- (23) Piminodine;
- (24) Racemethorphan;
- (25) Racemorphan;
- (26) Remifentanil;
- (27) Sufentanil; and
- (28) Tapentadol.

### **Section 4. Stimulants.**

The Cabinet for Health and Family Services designates as a Schedule II controlled substance a material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers (whether optical position or geometric), and salts of those isomers if the existence of the salts, isomers, or salts of isomers is possible within the specific chemical designation:

- (1) Amphetamine;
- (2) Methamphetamine;
- (3) Phenmetrazine;
- (4) Methylphenidate; and
- (5) Lisdexamfetamine.

### **Section 5. Depressants.**

(1) Except as provided in subsection (2) of this section, the Cabinet for Health and Family Services designates as a Schedule II controlled substance, in addition to those specified by KRS 218A.070, a material, compound, mixture, or preparation that contains a quantity of the following substances:

- (a) Amobarbital;
- (b) Glutethimide;
- (c) Pentobarbital;
- (d) Phencyclidine; and
- (e) Secobarbital.

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(2) A suppository dosage form containing amobarbital, secobarbital, or pentobarbital or any of their salts that has been approved by the United States Food and Drug Administration for marketing only as a suppository, shall be in Schedule III.

### **Section 6. Immediate Precursors.**

The Cabinet for Health and Family Services designates as a Schedule II controlled substance, in addition to those specified by KRS 218A.070, a material, compound, mixture, or preparation that contains a quantity of the following substances:

(1) Immediate precursors to amphetamine and methamphetamine and substances:

- (a) Phenylacetone;
- (b) Phenyl-2-propanone;
- (c) P2P;
- (d) Benzyl methyl ketone; and
- (e) Methyl benzyl ketone;

(2) Immediate precursors to phencyclidine:

- (a) 1-phenylcyclohexylamine; and
- (b) 1-piperidinocyclohexanecarbonitrile, also known as PCC; and
- (3) Immediate precursors of fentanyl, 4-anilino-N-phenethyl-4-piperidine (ANPP).

### **Section 7. Hallucinogenic Substances.**

The Cabinet for Health and Family Services designates as a Schedule II controlled substance, in addition to those specified by KRS 218A.070, a material, compound, mixture, or preparation that contains a quantity of Nabilone, also known as (plus or minus) - trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo{b,d}pyran-9-one.

(Recodified from 901 KAR 1:020, 4-14-1982; Am. 11 Ky.R. 1675; eff. 6-4-1985; 12 Ky.R. 1176; eff. 2-4-1986; 13 Ky.R. 1945; eff. 6-9-1987; 17 Ky.R. 3281; eff. 6-19-1991; 20 Ky.R. 859; eff. 12-6-1993; 26 Ky.R. 1237; 1561; eff. 2-1-2000; 42 Ky.R. 1975; eff. 3-4-2016.)

### **902 KAR 55:025. Schedule III substances.**

RELATES TO: KRS 218A.010-218A.030, 218A.080, 218A.090, 21 C.F.R. 1300.01, 21 C.F.R. 1308.01, 21 C.F.R. 1308.13, 21 C.F.R. 1308.34, 21 U.S.C. 801, 812

STATUTORY AUTHORITY: KRS 218A.020

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(1) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations in order to add, delete, or reschedule substances enumerated in KRS Chapter 218A. KRS 218A.020(3) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations to control substances controlled under federal law. This administrative regulation designates Schedule III controlled substances. This administrative regulation differs from the federal regulation because it designates pentazocine, barbitol, methylphenobarbital, and phenobarbital as a Schedule III controlled substance, and the federal regulation designates these substances as Schedule IV controlled substances. The Cabinet for Health and Family Services recognizes that pentazocine and derivatives of barbituric acid or its salts have significant abuse potential, and inclusion on Kentucky's Schedule III list will help reduce the risk to public health.

**Section 1. Amphetamine and Methamphetamine Combination Products.**

The Cabinet for Health Services designates the following amphetamine and methamphetamine combination products as Schedule III Controlled Substances:

- (1) A tablet or capsule containing:
  - (a) Methamphetamine hydrochloride 1 mg.;
  - (b) Conjugated estrogens-equine 0.25 mg.; and
  - (c) Methyl testosterone 2.5 mg; and
- (2) A liquid containing, in each 15 cc:
  - (a) Methamphetamine hydrochloride 1 mg.;
  - (b) Conjugated estrogens-equine 0.25 mg.; and
  - (c) Methyl testosterone 2.5 mg.

**Section 2. Stimulants.**

The Cabinet for Health Services designates as Schedule III controlled substances a material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers (whether optical position or geometric), and salts of those isomers if the existence of the salts, isomers or salts of isomers is possible within the specific chemical designation:

- (1) Benzphetamine;
- (2) Chlorphentermine;
- (3) Clortermine; and
- (4) Phendimetrazine.

**Section 3. Depressants.**

The Cabinet for Health and Family Services designates as Schedule III controlled substances the following:

- (1) A material, compound, mixture, or preparation containing amobarbital, secobarbital, or pentobarbital, or any of their salts, and at least one (1) other active medicinal ingredient which is not a controlled substance;
- (2) A suppository dosage form containing amobarbital, secobarbital, or pentobarbital, or any of their salts, which has been approved by the United States Food and Drug Administration for marketing only as a suppository;
- (3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof;
- (4) Chlorhexadol;
- (5) Embutramide;
- (6) A drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Chapter 9. Gamma hydroxybutyric acid is also known as:
  - (a) GHB;
  - (b) Gamma-hydroxybutyrate;
  - (c) 4-hydroxybutyrate;
  - (d) 4-hydroxybutanoic acid;
  - (e) Sodium oxybate; or
  - (f) Sodium oxybutyrate;
- (7) Ketamine, its salts, isomers, and salts of isomers. Ketamine is also known as (±)-2-(2-

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- chlorophenyl)-2-(methylamino)-cyclohexanone;
- (8) Lysergic acid;
- (9) Lysergic acid amide;
- (10) Methyprylon;
- (11) Perampanel and its salts, isomers, and salts of isomers;
- (12) Sulfondiethylmethane;
- (13) Sulfonethylmethane;
- (14) Sulfonmethane; and
- (15) Tiletamine and zolazepam or any of their salts.
  - (a) Tiletamine is also known as 2-(ethylamino)-2-(2-thienyl)-cyclohexanone.
  - (b) Zolazepam is also known as 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo- -diazepin-7(1H)-one, flupyrzapon.

### **Section 4. Pentazocine Drug Products.**

The Cabinet for Health Services designates, in addition to the parenteral or injectable form of Pentazocine which is designated as a Schedule III controlled substance by KRS 218A.090(3), a material, compound, mixture, or preparation which contains a quantity of Pentazocine, including its salts.

### **Section 5. Anabolic Steroids.**

- (1) The Cabinet for Health and Family Services designates as Schedule III Controlled Substances, in addition to those listed in KRS 218.090(5), any material, compound, mixture, or preparation containing any quality of an anabolic steroid as defined by 21 C.F.R. 1300.01, including its salts, esters, and ethers.
- (2) As used in this section, the term anabolic steroid shall not include an anabolic steroid:
  - (a) That is expressly intended for administration through implants to cattle or other nonhuman species; and
  - (b) That has been approved by the Secretary of the United States Department of Health and Human Services for administration as described in paragraph (a) of this subsection.
- (3) If any person prescribes, dispenses, or distributes a product identified in subsection (2) of this section for human use, the person shall be considered to have prescribed, dispensed, or distributed a Schedule III anabolic steroid.

### **Section 6. Hallucinogenic Substances.**

The Cabinet for Health Services designates as Schedule III controlled substances, in addition to those listed in KRS 218A.090, a material, compound, mixture, or preparation which contains a quantity of dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product. Dronabinol is also known as:

- (1) (6aR-trans)-6a, 7, 8, 10a- tetrahydro-6, 6, 9-trimethyl-3-pentyl-6H-dibenzo{b,d}pyran-1-ol; or
- (2) (-)- delta-9-(trans)- tetrahydrocannabinol.

### **Section 7. Narcotics.**

- 1) The Cabinet for Health and Family Services designates as Schedule III controlled substance any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as established in this subsection:

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- (a) Not more than one and four-fifths (1.8) grams of codeine per 100 milliliters or not more than ninety (90) milligrams per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium;
  - (b) Not more than one and four-fifths (1.8) grams of codeine per 100 milliliters or not more than ninety (90) milligrams per dosage unit with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts;
  - (c) Not more than one and four-fifths (1.8) grams of dihydrocodeine per 100 milliliters or not more than ninety (90) milligrams per dosage unit with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts;
  - (d) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than fifteen (15) milligrams per dosage unit with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts;
  - (e) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than twenty-five (25) milligrams per dosage unit with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts; and
  - (f) Not more than fifty (50) milligrams of morphine per 100 milliliters or per 100 grams with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (2) The Cabinet for Health and Family Services designates as Schedule III controlled substance a material, compound, mixture, or preparation which contains any quantity of buprenorphine, or its salts.

### **Section 8. Nalorphine.**

The Cabinet for Health and Family Services designates as Schedule III controlled substance a material, compound, mixture, or preparation which contains any quantity of nalorphine or its salts.

(Recodified from 901 KAR 1:025, 4-14-1982; Am. 11 Ky.R. 1676; eff. 6-4-1985; 13 Ky.R. 1946; eff. 6-9-1987; 15 Ky.R. 865; eff. 11-4-1988; 17 Ky.R. 3283; eff. 6-19-1991; 20 Ky.R. 861; eff. 12-6-1993; 26 Ky.R. 1238; 1562; eff. 2-1-2000; 29 Ky.R. 817; 1277; eff. 10-16-2002; 42 Ky.R. 1977; eff. 3-4-2016.)

### **902 KAR 55:030. Schedule IV substances.**

RELATES TO: KRS 218A.010-218A.030, 218A.100, 218A.110, 21 C.F.R. 1308.14, 21 U.S.C. 801, 812

STATUTORY AUTHORITY: KRS 218A.020

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(1) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations to add, delete, or reschedule substance enumerated in KRS Chapter 218A. KRS 218A.020(3) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations to control substances controlled under federal law. This administrative regulation designates Schedule IV controlled substances. This administrative regulation differs from the federal regulation because it designates nalbuphine as a Schedule IV controlled substance. The Cabinet for Health and Family Services recognizes that nalbuphine has significant abuse potential, and inclusion on Kentucky's Schedule IV list will help reduce the risk to public health.

### **Section 1. Stimulants.**

The Cabinet for Health and Family Services designates as Schedule IV controlled substances, in addition to those specified by KRS 218A.110, a material, compound, mixture, or preparation

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which contains a quantity of the following substances, including their salts, isomers whether optical, position, or geometric, and salts of the isomers, if the existence of the salts, isomers, and salts of isomers is possible:

- (1) Cathine ((+)-norpseudoephedrine);
- (2) Diethylpropion;
- (3) Fencamfamin;
- (4) Fenproporex;
- (5) Mazindol;
- (6) Mefenorex;
- (7) Modafinil;
- (8) Pemoline, including organometallic complexes and chelates;
- (9) Phentermine;
- (10) Pipradrol;
- (11) Sibutramine; and
- (12) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

### **Section 2. Depressants.**

The Cabinet for Health and Family Services designates as Schedule IV controlled substances, in addition to those specified by KRS 218A.110, a material, compound, mixture, or preparation which contains a quantity of the following substances, including its salts, isomers, and salts of isomers if the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Alfaxalone;
- (2) Alprazolam;
- (3) Bromazepam;
- (4) Camazepam;
- (5) Carisoprodol;
- (6) Chloral betaine;
- (7) Chloral hydrate;
- (8) Chlordiazepoxide;
- (9) Clobazam;
- (10) Clonazepam;
- (11) Clorazepate;
- (12) Clotiazepam;
- (13) Cloxazolam;
- (14) Delorazepam;
- (15) Diazepam;
- (16) Dichloralphenazone;
- (17) Estazolam;
- (18) Ethchlorvynol;
- (19) Ethinamate;
- (20) Ethyl loflazepate;
- (21) Fludiazepam;
- (22) Flunitrazepam;
- (23) Flurazepam;
- (24) Fospropofol;



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- (25) Halazepam;
- (26) Haloxazolam;
- (27) Ketazolam;
- (28) Loprazolam;
- (29) Lorazepam;
- (30) Lormetazepam;
- (31) Mebutamate;
- (32) Medazepam;
- (33) Meprobamate;
- (34) Methohexital;
- (35) Midazolam;
- (36) Nimetazepam;
- (37) Nitrazepam;
- (38) Nordiazepam;
- (39) Oxazepam;
- (40) Oxazolam;
- (41) Paraldehyde;
- (42) Petrichloral;
- (43) Pinazepam;
- (44) Prazepam;
- (45) Quazepam;
- (46) Suvorexant;
- (47) Temazepam;
- (48) Tetrazepam;
- (49) Triazolam;
- (50) Zaleplon;
- (51) Zolpidem; and
- (52) Zopiclone.

### **Section 3. Fenfluramine.**

The Cabinet for Health and Family Services designates as Schedule IV controlled substances, in addition to those specified by KRS 218A.110, a material, compound, mixture, or preparation which contains any quantity of Fenfluramine, including its salts, isomers, whether optical, position, or geometric, and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible.

### **Section 4. Lorcaserin.**

The Cabinet for Health and Family Services designates as Schedule IV controlled substances, in addition to those specified by KRS 218A.110, a material, compound, mixture, or preparation that contains any quantity of lorcaserin, including its salts, isomers, and salts of isomers, if the existence of these salts, isomers, and salts of isomers is possible.

### **Section 5. Narcotics.**

The Cabinet for Health and Family Services designates as Schedule IV controlled substances, in addition to those specified by KRS 218A.110, a material, compound, mixture, or preparation containing a quantity of the following narcotic drugs, or their salts calculated as the free

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anhydrous base or alkaloid, as set forth below:

- (1) Butorphanol (including its optical isomers);
- (2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane);
- (3) Not more than one (1) milligram of difenoxin and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit;
- (4) Nalbuphine; and
- (5) 2--1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers, including tramadol.

(Recodified from 901 KAR 1:030, 4-14-1982; Am. 11 Ky.R. 1678; eff. 6-4-1985; 12 Ky.R. 1177; eff. 2-4-1986; 13 Ky.R. 1948; eff. 6-9-1987; 15 Ky.R. 866; eff. 11-4-1988; 20 Ky.R. 862; 1701; eff. 2-10-1994; 22 Ky.R. 1900; 2302; eff. 6-6-1996; 25 Ky.R. 627; 1630; eff. 1-19-1999; 26 Ky.R. 902; 1170; eff. 12-15-1999; 29 Ky.R. 819; 1277; eff. 10-16-2002; 33 Ky.R. 1436; 1820; eff. 2-2-2007; 34 Ky.R. 2607; 35 Ky.R. 1198; eff. 12-5-2008; 42 Ky.R. 1980; eff. 3-4-2016.)

### **902 KAR 55:035. Schedule V substances.**

RELATES TO: KRS 217.005 - 217.215, 218A.010-218A.030, 218A.120, 218A.130, 21 C.F.R. 1308.15, 21 U.S.C. 301 - 399f, 21 U.S.C. 812

STATUTORY AUTHORITY: KRS 218A.020

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(1) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations to add, delete, or reschedule substances enumerated in KRS Chapter 218A. KRS 218.020(3) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations to control substances controlled under federal law. This administrative regulation designates Schedule V controlled substances.

#### **Section 1. Schedule V Controlled Substances.**

The Cabinet for Health and Family Services hereby designates as Schedule V controlled substances, in addition to those specified by KRS 218A.130, the following:

(1) Narcotic drugs containing nonnarcotic active medicinal ingredients. A compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

- (a) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;
  - (b) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;
  - (c) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;
  - (d) Not more than two and five-tenths (2.5) milligrams of diphenoxylate and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit;
  - (e) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams; and
  - (f) Not more than five-tenths (0.5) milligram of difenoxin and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit;
- (2) Stimulants. A material, compound, mixture, or preparation which contains any quantity of the

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following substance having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers: Pyrovalerone; and

(3) Depressants. A material, compound, mixture, or preparation which contains any quantity of the following substance having a depressant effect on the central nervous system, including its salts:

- (a) Ezogabine -carbamic acid ethyl ester];
- (b) Lacosamide; and
- (c) Pregabalin.

### **Section 2. Dispensing Without Prescription.**

A controlled substance listed in Schedule V which is not a prescription drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 to 399f, may be dispensed by a pharmacist without a prescription to a purchaser at retail, if:

- (1) The medicinal preparation contains in addition to the controlled substances, some drug or drugs conferring upon it medicinal qualities other than those possessed by the controlled substances alone;
- (2) Not more than 240cc (eight (8) ounces) nor more than forty-eight (48) dosage units of any such controlled substance containing opium, is dispensed at retail to the same purchaser in any given forty-eight (48) hour period;
- (3) The labeling and packaging is in accordance with the requirements of the federal and state Food, Drug, and Cosmetic Act and the United States Pharmacopeia;
- (4) The preparation is dispensed or sold in good faith as a medicine, and not for the purpose of evading the provisions of KRS Chapter 218A;
- (5) The preparation is not displayed in areas open to the public;
- (6) The dispensing is made only by a pharmacist, and not by a nonpharmacist employee even if under the supervision of a pharmacist. Although, after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist;
- (7) The purchaser is at least eighteen (18) years of age;
- (8) The pharmacist requires every purchaser of a controlled substance under this section, not known to him, to furnish suitable identification, including proof of age if appropriate; and
- (9) The dispensing of exempt controlled substances under this administrative regulation is recorded in a bound book, maintained by the pharmacist, which shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser. The book shall be maintained in accordance with the recordkeeping requirements of KRS 218A.200.

(Recodified from 901 KAR 1:032, 4-14-1982; Am. 11 Ky.R. 1679; eff. 6-4-1985; 15 Ky.R. 868; eff. 11-4-1988; 20 Ky.R. 660; eff. 10-21-1993; 29 Ky.R. 1407; eff. 1-15-2003; 33 Ky.R. 1438; 1821; eff. 2-2-2007; 42 Ky.R. 1982; eff. 3-4-2016.)

### **902 KAR 55:040. Excluded over-the-counter products.**

RELATES TO: KRS 218A.020-218A.130

STATUTORY AUTHORITY: KRS 194.050, 211.090, 218A.020, 218A.250, EO-96-862

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NECESSITY, FUNCTION, AND CONFORMITY: Executive Order 96-862, effective July 2, 1996, reorganizes the Cabinet for Human Resources, establishes and creates the Cabinet for Health Services, changes the name of the Department for Health Services to Department for Public Health, and places the Department for Public Health and its programs under the Cabinet for Health Services. KRS 218A.020(4) requires the Cabinet for Health Services to exclude products that may be lawfully sold over the counter (without prescription) from the provisions of KRS Chapter 218A. The purpose of this administrative regulation is to exclude certain over-the-counter products from the provisions of KRS Chapter 218A.

### **Section 1. Excluded Over-the-counter Products.**

The Cabinet for Health Services excludes the following products from the provisions of KRS Chapter 218A:

- (1) Asthma-Ese®, tablet, NDC code 00349-2018: phenobarbital 8.10 mg.;
- (2) Azma-Aids®, tablet, NDC code 00367-3153: phenobarbital 8 mg;
- (3) Bronkolixir®, elixir, NDC code 00057-1004: phenobarbital 0.8 mg/ml;
- (4) Bronkotabs®, tablet, NDC code 00057-1005: phenobarbital 8 mg.;
- (5) Choate's Leg Freeze®, liquid: chloral hydrate 246.67 mg/ml.;
- (6) Guiaphed® Elixir, elixir, NDC code 00182-1377: phenobarbital 4 mg/ml;
- (7) Primatene (P-tablets)®, tablet, NDC code 0573-2940: phenobarbital 8 mg.;
- (8) Tedral®, tablet, NDC code 00071-1230: phenobarbital 8 mg.;
- (9) Tedral Elixir®, elixir, NDC code 00071-0242: phenobarbital 40 mg./ml.;
- (10) Tedral S.A.®, tablet, NDC code 00071-1231: phenobarbital 8 mg.;
- (11) Tedral Suspension®, suspension, NDC code 00071-0237: phenobarbital 80 mg./ml.;
- (12) Tedrigen®, tablet, NDC code 00182-0134: phenobarbital 8 mg.;
- (13) Theophed®, tablet, NDC code 00719-1945: phenobarbital 8 mg; and
- (14) Vicks Inhaler®, inhaler, NDC code 23900-0010: l-Desoxyephedrine 113 mg. (Recodified from 901 KAR 1:040, 4-14-82; Am. 11 Ky.R. 1679; eff. 6-4-85; 18 Ky.R. 1471; eff. 2-7-92; 19 Ky.R. 1665; 2251; eff. 3-17-93; 20 Ky.R. 863; eff. 12-6-93; 21 Ky.R. 1393; eff. 1-9-95; 23 Ky.R. 3985; 24 Ky.R. 126; eff. 7-16-97.)

### **902 KAR 55:045. Exempt prescription products.**

RELATES TO: KRS 218A.020-218A.250, 21 C.F.R. 1308.31-1308.32

STATUTORY AUTHORITY: KRS 218A.020

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(3) provides that if a controlled substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice is given to the Cabinet for Health and Family Services, the Cabinet for Health and Family Services may similarly control the substance under KRS Chapter 218A by administrative regulation. This administrative regulation exempts prescription products from the licensing, distribution, recordkeeping, and reporting provisions of KRS Chapter 218A if the products have received approval as an exempt prescription product pursuant to 21 C.F.R. 1308.32.

#### **Section 1. Exempt Prescription Products.**

- (1) Except as provided by subsection (2) of this section, the Cabinet for Health and Family Services exempts prescription products from the licensing, distribution, recordkeeping, and reporting provisions of KRS 218A.150 – 218A.172, 218A.180, 218A.200, and 218A.202 if the products have

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received approval as exempt prescription products pursuant to 21 C.F.R. 1308.32.

(2) All products containing butalbital shall:

(a) Be reported to the Kentucky All-Schedule Prescription Electronic Reporting System in accordance with the requirements established in 902 KAR 55:110; and

(b) Not be exempt from the licensing, distribution, and recordkeeping provisions of KRS 218A.150 – 218A.172, 218A.180, and 218A.200.

(Recodified from 901 KAR 1:041, 4-14-1982; Am. 11 Ky.R. 1680; eff. 6-4-1985; 18 Ky.R. 1472; eff. 2-7-1992; 19 Ky.R. 1666; 2251; eff. 3-17-1993; 20 Ky.R. 864; eff. 12-6-1993; 21 Ky.R. 1394; eff. 1-9-1995; 23 Ky.R. 4228; eff. 7-16-1997; 25 Ky.R. 629; 1631; eff. 1-19-1999; 26 Ky.R. 903; 1171; eff. 12-15-1999; 40 Ky.R. 2635; 41 Ky.R. 290; eff. 9-17-2014.)

### **902 KAR 55:060. Requirements for distribution of small amounts of controlled substances without manufacturer's or wholesaler's licenses.**

RELATES TO: KRS 218A.010-218A.020, 218A.150-218A.200, 21 C.F.R. 1304.03, 1305.03, 1307.11

STATUTORY AUTHORITY: KRS 194.050, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.250 directs the Cabinet for Human Resources to adopt rules and administrative regulations for carrying out the provisions of KRS Chapter 218A relating to controlled substances. KRS 218A.170(2) provides that all sales and distributions of controlled substances shall be in accordance with the federal controlled substances laws, including the requirements governing the use of order forms. The purpose of this administrative regulation is to provide for the distribution of small amounts of controlled substances by pharmacies to practitioners or other pharmacies, without the necessity of obtaining a state license as a manufacturer or a wholesaler, in accordance with applicable federal laws and regulations.

#### **Section 1. Distribution of Controlled Substances by Pharmacy to Practitioner or other Pharmacy.**

(1) A pharmacy may distribute a quantity of a controlled substance to a practitioner or another pharmacy, without being licensed as a manufacturer or wholesaler in Kentucky if it:

(a) Is licensed in Kentucky;

(b) Is registered with the U.S. Drug Enforcement Administration; and

(c) Makes the distribution to a practitioner or pharmacy that is registered with the U.S. Drug Enforcement Administration.

(2) The distribution shall be recorded by the distributing pharmacy and by the receiving practitioner or pharmacy in accordance with KRS 218A.200;

(3) A readily retrievable record of the distribution shall be maintained showing:

(a) Date of distribution;

(b) Name, form and quantity of the substance distributed; and

(c) Name, address and registration number of the purchaser.

(4) The total number of dosage units of all controlled substances distributed by a pharmacy pursuant to this administrative regulation during a twelve (12) month period shall not exceed five (5) percent of the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the twelve (12) month period. If the five (5) percent limitation is expected to be exceeded, the pharmacy shall obtain a license to distribute controlled substances in accordance with KRS 218A.160 and 218A.170; and

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(5) A prescription shall not be issued by a practitioner to obtain any controlled substance for the purpose of general dispensing, administering or office use.

(Recodified from 901 KAR 1:070, 4-14-82; Am. 11 Ky.R. 1681; eff. 6-4-85; 18 Ky.R. 1244; 1890; eff. 11-25-91; 20 Ky.R. 1425; eff. 1-10-94.)

### **902 KAR 55:065. Return of prescription drugs prohibited, exceptions.**

RELATES TO: KRS 217.005-217.215, 217.992

STATUTORY AUTHORITY: KRS 194.050, 211.090, 217.125

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125 authorizes the Cabinet for Human Resources to administer the provisions of KRS 217.005 to 217.215 and 217.992. The purpose of this administrative regulation is to prevent the dispensing of prescription drugs that may be adulterated or misbranded.

#### **Section 1. Return of Prescription Drugs Prohibited; Exceptions.**

(1) No pharmacist, practitioner, or agent thereof shall accept the return of a prescription drug for reuse or resale unless:

(a) The drug is in a sealed container by which it can be readily determined by a pharmacist employed by the dispensing pharmacy or by the dispensing practitioner that entry or attempted entry by any means has not been made;

(b) The drug container meets the standards of the United States Pharmacopoeia for storage conditions including temperature, light sensitivity, moisture, chemical, and physical stability;

(c) The drug labeling and packaging has not been altered or defaced and the identity of the drug, its potency, lot number, and expiration date are legible;

(d) The drug does not require refrigeration; and

(e) The drug is returned to a pharmacist employed by the dispensing pharmacy or to the dispensing practitioner within fourteen (14) days.

(2) Subsection (1)(d) and (e) of this section shall be waived if all other conditions are met and if:

(a) The drug was dispensed for a patient in a health care facility licensed by the Cabinet for Human Resources;

(b) The drug has not come into the physical possession of the person for whom it was prescribed;

(c) The drug has been under the continuous control of personnel in the health care facility who are trained and knowledgeable in the storage and administration of drugs;

(d) The drug has been properly stored in an area which is regularly inspected by a pharmacist; and

(e) The drug is not expired.

(3) Drugs distributed within an acute care facility shall be exempt from the provisions of subsection (1)(a), (d) and (e) of this section.

(4) Nothing in this administrative regulation shall be construed to require a pharmacist or practitioner to accept the return of a prescription drug

. (15 Ky.R. 1618; Am. 1853; eff. 3-15-89; 20 Ky.R. 2226; eff. 3-14-94.)

**902 KAR 55:070. Storage of controlled substances in an emergency medication kit in certain long-term care facilities.**

RELATES TO: KRS 218A.180, 218A.200

STATUTORY AUTHORITY: KRS 194A.050 194.050, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.250 directs the Cabinet for Health and Family Services to adopt rules and administrative regulations for carrying out the provisions of KRS Chapter 218A relating to controlled substances. This administrative regulation authorizes the storage in an emergency medication kit in certain long-term care facilities of limited quantities of controlled substances to be administered if prescribed by an authorized practitioner.

**Section 1.**

Storage of Controlled Substances in an Emergency Medication Kit.

A pharmacy provider may store controlled substances in an emergency medication kit in a residential hospice facility, nursing home, nursing facility, skilled nursing facility, intermediate care facility, or intermediate care facility for the mentally retarded if the following conditions are met:

- (1) Written policies and procedures of the facility regarding the procurement, use, storage, security, replacement, and recordkeeping of controlled substances in the kit shall be filed with the facility and with the provider pharmacy;
- (2) Controlled substances in the kit shall be the property of the provider pharmacy, which is responsible for their proper labeling, storage, security, and accountability;
- (3) Controlled substances stored in the kit shall be selected jointly by the facility's medical director or other physician, consultant pharmacist, and the director of nursing;
- (4) Controlled substances in the kit shall not exceed six (6) individual doses each of six (6) different controlled substances;
- (5) Controlled substances in the kit shall be administered only upon the order of an authorized practitioner who determines that the patient has an immediate medical need;
- (6) Access to the controlled substances in the kit shall be limited to a physician, pharmacist, registered nurse, or other person authorized by law in this state to access and administer the prescribed medication;
- (7) The provider pharmacy shall be notified by the facility within twenty-four (24) hours after the kit has been opened;
- (8) The prescribing practitioner shall issue a written prescription for the controlled substances to the provider pharmacy within seventy-two (72) hours after administration of a controlled substance from the kit;
- (9) The facility shall maintain a record of the administration of controlled substances from the kit in accordance with applicable state and federal laws;
- (10) The provider pharmacy shall document documents a physical inventory of the controlled substances in the kit at least monthly; and
- (11) The loss of any controlled substance from the kit shall be reported to the Cabinet for Health and Family Services in accordance with KRS 218A.200(6) and to the Federal Drug Enforcement Administration in accordance with 21 C.F.R. 1301.74(c).

**Section 2.**

The Cabinet for Health and Family Services may deny, suspend, or revoke the privilege of storing controlled substances in an emergency medication kit if any provision in Section 1 of this administrative regulation is violated.

All administrative hearings shall be conducted in accordance with 902 KAR 1:400.

(15 Ky.R. 1352; eff. 12-13-88; Am. 20 Ky.R. 2227; eff. 3-14-94; 22 Ky.R. 2481; eff. 8-1-96; 33 Ky.R. 2218; 2973; eff. 4-6-07.)

**902 KAR 55:075. Sale of seized and forfeited controlled substances.**

RELATES TO: KRS Chapter 218A

STATUTORY AUTHORITY: KRS 194.050, 218A.250, 218A.420(2)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.420(2) directs the Cabinet for Human Resources to promulgate administrative regulations to determine a proper buyer for controlled substances which are seized and forfeited under this chapter. The purpose of this administrative regulation is to prevent the sale of controlled substances that may be adulterated or misbranded.

**Section 1. Sale of Seized and Forfeited Controlled Substances.**

A person shall not sell or purchase controlled substances which have been seized and forfeited under KRS Chapter 218A unless, prior to the sale:

- (1) A written request for permission to sell or purchase such controlled substances is made to the Cabinet for Human Resources, Drug Control Branch; and
- (2) The controlled substances are inspected by a pharmacist of the Cabinet for Human Resources, Drug Control Branch; and
- (3) If a pharmacist of the Cabinet for Human Resources, Drug Control Branch, has made a written determination that tests or assays are necessary in order to determine whether the controlled substances have been adulterated or misbranded under the provisions of KRS 217.055 and 217.065, the person who submitted the request:
  - (a) Has had such tests or assays performed at his expense;
  - (b) Certified and submitted the results of such tests or assays to the pharmacist; and
  - (c) Has taken action required by the pharmacist after his review of the results of tests or assays that have been certified and submitted; and
- (4) The person who submitted the request specifies the buyer and certifies that the buyer is:
  - (a) Licensed under the provisions of applicable statutes of the Commonwealth of Kentucky to perform the following acts related to controlled substances:
    1. Administer;
    2. Conduct chemical analysis;
    3. Conduct research;
    4. Dispense;
    5. Distribute;
    6. Manufacture;
    7. Prescribe; or
    8. Repackage; and
  - (b) Registered with the Drug Enforcement Administration, U.S. Department of Justice; and



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(5) Permission is granted, in writing, by the Cabinet for Human Resources. (17 Ky.R. 3606; Am. 18 Ky.R. 703; eff. 8-21-91.)

### **902 KAR 55:080. Written prescriptions to be signed by practitioner.**

RELATES TO: KRS Chapter 218A

STATUTORY AUTHORITY: KRS 194.050, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.250 directs the Cabinet for Human Resources to adopt rules and administrative regulations for carrying out the provisions of KRS Chapter 218A relating to controlled substances. The purpose of this administrative regulation is to clarify who is authorized to sign a prescription for controlled substances and the form of the signature, which must be in accordance with federal regulation.

**Section 1.** A written prescription for a controlled substance shall be signed only by a practitioner who is authorized to prescribe controlled substances under the laws of the jurisdiction in which he is licensed to practice his profession.

**Section 2.** A written prescription for a controlled substance shall be written with ink, indelible pencil or typewriter and may be prepared by an agent for the practitioner's signature. The prescription shall be manually signed by the practitioner which may be in the same manner as he would sign a check or legal document. (17 Ky.R. 3607; eff. 7-17-91.)

### **902 KAR 55:090. Exempt anabolic steroid products.**

RELATES TO: KRS 218A.010-218A.250, 21 C.F.R. 1308.13, 1308.33-1308.34, 21 U.S.C. 801, 812

STATUTORY AUTHORITY: KRS 218A.020

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020 authorizes the Cabinet for Health and Family Services to add, delete, or reschedule substances enumerated in KRS Chapter 218A. This administrative regulation exempts certain anabolic steroid products from the licensing, distribution, recordkeeping, and reporting provisions of KRS Chapter 218A if the products have received approval as an exempt anabolic steroid product pursuant to 21 C.F.R. 1308.34.

**Section 1.** Exempt Anabolic Steroid Products. The Cabinet for Health and Family Services exempts anabolic steroid products from the licensing, distribution, recordkeeping, and reporting provisions of KRS 218A.150 – 218A.172, 218A.180, 218A.200, and 218A.202 if the products have received approval as exempt anabolic steroid products pursuant to 21 C.F.R. 1308.34. (19 Ky.R. 2207; eff. 4-21-1993; Am. 21 Ky.R. 1395; eff. 1-9-1995; 23 Ky.R. 3986; eff. 7-16-1997; 26 Ky.R. 907; 1174; eff. 12-15-1999; 29 Ky.R. 820; 1278; eff. 10-16-2002; 40 Ky.R. 2639; eff. 9-17-2014.)

### **902 KAR 55:095. Prescription for Schedule II controlled substance - facsimile transmission or partial filling.**

RELATES TO: KRS 218A.070, 218A.180, 218A.200, 21 C.F.R. 1306.05, 1306.11-1306.14

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STATUTORY AUTHORITY: KRS 194.050, 218A.250, EO 96-862

NECESSITY, FUNCTION, AND CONFORMITY: Executive Order 96-862, effective July 2, 1996, reorganizes the Cabinet for Human Resources, establishes and creates the Cabinet for Health Services, changes the name of the Department for Health Services to Department for Public Health, and places the Department for Public Health and its programs under the Cabinet for Health Services. KRS 218A.250 directs the Cabinet for Health Services to promulgate administrative regulations for carrying out the provisions of KRS Chapter 218A relating to controlled substances. The purpose of this administrative regulation is to permit the transmission of prescriptions for Schedule II controlled substances between the prescriber and dispenser via facsimile, on a limited basis, in order to facilitate the delivery of medications to certain patients whose medication needs change quickly and whose prescription should be communicated rapidly. This administrative regulation also permits the partial filling of prescriptions for Schedule II controlled substances to certain patients whose medication needs may be long term but who wish to store limited quantities or in situations where the pharmacy is unable to supply the full quantity prescribed.

### **Section 1. Definitions.**

- (1) "Hospice" means a hospice program licensed by the Cabinet for Health Services.
- (2) "Long-term care facility" means a nursing home, skilled nursing facility, nursing facility as defined in Pub.L. 100-203, intermediate care facility, or intermediate care facility for the mentally retarded.

**Section 2. Transmission by Facsimile of a Prescription for a Schedule II Controlled Substance.** (1) A prescription prepared in accordance with KRS 218A.180, 21 C.F.R. 1306.05 and 902 KAR 55:080 for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by a practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

- (2) A prescription prepared in accordance with KRS 218A.180, 21 C.F.R. 1306.05 and 902 KAR 55:080 for a Schedule II controlled substance for a resident of a long-term care facility may be transmitted by a practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.
- (3) A prescription prepared in accordance with KRS 218A.180, 21 C.F.R. 1306.05 and 902 KAR 55:080 for a schedule II controlled substance for a hospice patient may be transmitted by a practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient.
- (4)
  - (a) The facsimile prescription shall serve as the written prescription, required by KRS 218A.180(1) for the dispensing of a Schedule II controlled substance.
  - (b) Within seven (7) calendar days after transmitting a facsimile prescription for a Schedule II controlled substance, the prescribing practitioner shall deliver the original written prescription to the dispensing pharmacy.
  - (c) A practitioner who fails to deliver the original written prescription within the period specified in paragraph (b) of this subsection shall be deemed to have violated KRS 218A.1404(3).

### **Section 3. Partial Filling of a Prescription for a Schedule II Controlled Substance.**

- (1) Except as provided in subsection (2) of this section a pharmacist may partially fill a prescription for a controlled substance listed in Schedule II if the pharmacist:

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- (a) Is unable to dispense the full quantity prescribed;
  - (b) Makes a notation of the quantity dispensed on the face of the written prescription; and
  - (c) Dispenses the remaining portion of the prescription within seventy-two (72) hours of the first partial filling. No further quantity shall be dispensed without a new written prescription.
- (2) A written prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a documented terminal illness may be dispensed in partial quantities, including but not limited to individual dosage units if:
- (a) The pharmacist records on the face of the prescription whether the patient is "terminally ill" or an "LTCF patient";
  - (b) The pharmacist records on the back of the written prescription or on another appropriate record, uniformly maintained and readily retrievable, the following data:
    - 1. The date of the partial dispensing;
    - 2. The quantity dispensed;
    - 3. The remaining quantity authorized to be dispensed; and
    - 4. The identification of the dispensing pharmacist;
  - (c) The pharmacist contacts the practitioner prior to dispensing the partial quantity if there is any question whether the patient is terminally ill, since both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient;
  - (d) The total quantity dispensed in all partial dispensings does not exceed the quantity prescribed; and
  - (e) No dispensing occurs beyond sixty (60) days from date of issuance of the prescription.
- (3) A prescription that is partially filled and does not comply with the requirements of subsection (1) or (2) of this section shall be deemed to have been filled in violation of KRS 218A.200(3), (4) and 21 C.F.R. 1306.13.
- (21 Ky.R. 2589; Am. 22 Ky.R. 291; eff. 7-26-95; 24 Ky.R. 1165; eff. 1-12-98.)

### **902 KAR 55:100. Laetrile manufacturing standards.**

RELATES TO: KRS 217.950, 217.952, 311.950-311.966, 311.991

STATUTORY AUTHORITY: KRS 194.050, 217.950, EO 96-862

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.950 provides that Amygdalin (laetrile) may be manufactured in this state subject to licensing by the Cabinet for Human Resources and directs the Secretary for Human Resources to adopt administrative regulations which prescribe minimum standards for manufacturers in preparing, compounding, processing, and packaging the substance. The secretary is also directed to establish standards of purity and make periodic tests and inspections of both the facilities for manufacture and samples to ascertain the purity, quality, and identity. Executive Order 96-862, effective July 2, 1996, reorganizes the Cabinet for Human Resources and places the Department for Public Health and its programs under the Cabinet for Health Services.

#### **Section 1. Intent.**

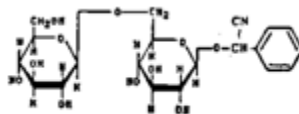
In adopting an administrative regulation relating to the manufacture of Amygdalin (laetrile), the Cabinet for Health Services takes official notice that this substance has not been approved by the Federal Food and Drug Administration and that the interstate shipment of the substance has been

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held to be illegal. This administrative regulation is adopted in recognition of existing federal restrictions.

### Section 2. Definitions.

(1) "Amygdalin", laetrile means Amygdalin, D-mandelonitrile-beta-D-glucoside-6-beta-D-Glucoside, including all dosage forms.



It includes:

- (a) D-Amygdalin; and
  - (b) D, L-Amygdalin.
- (2) "Cabinet" means the Cabinet for Health Services.
- (3) "Current good manufacturing practices" means 21 CFR 210.1 to 210.3 - Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding of Drugs and 21 CFR 211.1 to 211.208 - Current Good Manufacturing Practice for Finished Pharmaceuticals adopted by the U.S. Food and Drug Administration.

### Section 3. Licensing Requirements.

- (1) A person, partnership, association, corporation, or other business organization shall not manufacture, prepare, or compound Amygdalin in this state without a license from the cabinet.
- (2) Application for a license shall be made on Form DCB-1, "Application for License to Manufacture Amygdalin", provided by the cabinet, and shall include the training and experience of personnel and a description of the facilities, equipment, and materials to be used in the manufacture of Amygdalin.
- (3) A license shall not be issued to manufacture Amygdalin unless the applicant:
- (a) Is of good moral character, or if the applicant is an association or corporation, its officers are of good moral character;
  - (b) Is in compliance with "Current Good Manufacturing Practices";
  - (c) Has qualified personnel to perform assigned tasks;
  - (d) Submits the formula, including all components, involved in the manufacture of the product;
  - (e) Submits a label which discloses all information required for a prescription drug, including a disclosure of possible side effects;
  - (f) Is financially responsible; and
  - (g) Is in compliance with all provisions of this administrative regulation.

### Section 4. License Expiration; Renewal.

- (1) Every license issued by the cabinet to manufacture Amygdalin shall expire on June 30 of each year following the date of issuance unless suspended or revoked.
- (2) A license shall not be renewed by the cabinet to manufacture Amygdalin unless the applicant is in compliance with the provisions of this administrative regulation.

**Section 5. Manufacturing Practices.**

The current good manufacturing practices in manufacturing, processing, packing, or holding of drugs in 21 CFR 210.1 to 210.3 and the current good manufacturing practice for finished pharmaceuticals in 21 CFR 211.1 to 211.208 adopted by the U.S. Food and Drug Administration shall apply.

**Section 6. Standards of Identity, Purity, and Tests for D-Amygdalin.**

## (1) Powder form:

(a) Molecular formula:  $C_{20}H_{27}NO_{11}$ ;

(b) Molecular weight: 457.4;

(c) Description: White powder - melting range: varies with water of crystallization and previous melting;

(d) Solubility: (mg/ml) water 125, ethanol 0.33, ten (10) percent ethanol 20, ether insoluble, methylene chloride insoluble;

(e) Stability:

1. Solution: (10 mg/ml) Determined by gas chromatography of TMS derivative:

pH 6 phosphate buffer	Stable at least twenty-four (24) hours
pH 8 phosphate buffer	No more than fifteen (15) percent L-Amygdalin formed in twenty-four (24) hours
0.1 N HCl	No more than sixty-five (65) percent decomposition in ten (10) minutes
0.1 N NaOH	No more than fifty-six (56) percent decomposition in ten (10) minutes

2. Bulk: A sample stored at sixty (60) degrees Celsius for thirty (30) days showed no degradation as indicated by gas chromatography;

(f) Elemental composition:

Carbon	52.51
Hydrogen	5.95
Nitrogen	3.06
Oxygen	38.48

(g) Water: The compound shall not contain more than six (6) percent water, determined by Karl-Fischer;

(h) Infrared spectrum: The infrared spectrum conforms to reference material;

(i) Ultraviolet absorption: ( $H_2O$ ) a solution has the following absorption peaks ( $\alpha$  max) and extinction coefficients (E):

$\alpha$ max	E
268 nm	214
262 nm	312

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257 nm	287
252 nm	203
208 nm	7400

(j) Nuclear magnetic resonance: (D<sub>2</sub>O)

Chemical Shift (δ)	Pattern	No. Protons	Assignment
3.2-5.2	m	14	Glucosyl protons
5.9	s	1	H - C - C = N
7.6	s	5	Phenyl protons

(k) Optical rotation:

$$[\alpha]_{\text{D}}^{20} = -42^{\circ} (1, \text{H}_2\text{O})$$

Merck Index, 8th Ed. (1968);

(l) Gas chromatography:

1. Column: three (3) percent OV-1 on 100/200 Chromosorb W, AW-DMCS in glass column;
2. Oven temperature: 250 degrees to 275 degrees Celsius programmed at one (1) degree per minute;
3. Carrier gas: N<sub>2</sub>, thirty-five (35) ml. per minute;
4. Sample: TMS-derivative of the sample (Prepare by dissolving one (1) mg. of the sample in five-tenths (0.5) ml. tri-sil with gentle heat.);
5. Detection: Flame ionization at 300 degrees Celsius;

(m) Thin layer chromatography:

1. Adsorbent: SiO<sub>2</sub>·HF;
2. Solvent system: n-BuOH/HOAc/H<sub>2</sub>O (6:3:1);
3. Sample applied: 100Y, 200Y, (H<sub>2</sub>O);
4. Detection: UV, I<sub>2</sub>, KBR Spray;

(n) Purity: The compound shall not contain more than one (1) percent total impurities other than water;

(o) Suggested identity tests: IR, UV & NMR Spectra; and

(p) Suggested assay procedures: Thin layer and gas chromatography.

(2) Tablet form:

TEST	SPECIFICATION
Assay:	Ninety (90)-110 percent of label

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HPLC Method Column-Lichrosorb RP8, 300 mm. x 4 mm. Mobile phase 25% CH <sub>3</sub> OH in H <sub>2</sub> O Flow rate - 2 ml./min. Detector/sensitivity-uv at 254 nm/0.02 aufs	The total of all uv absorbing impurities shall not exceed five (5) of this chromatogram
Disintegration: Current USP method	100% within fifteen (15) minutes
Dissolution: Current USP method	100% within thirty (30) minutes
Weight variation	Conforms to current USP
Thin layer chromatography (Methanol extraction) Adsorbent: Silica gel GF Solvent system: n-BuOH/HOAc/H <sub>2</sub> O, 4/1/1 Sample applied: 200, 100Y (MeOH) References: D,L-Amygdalin, 100Y (H <sub>2</sub> O) D,L-Amygdalinamide, 2, 4Y (H <sub>2</sub> O) D,L-Amygdalin acid, 3, 5Y (H <sub>2</sub> O) Detection: uv, I <sub>2</sub> , H <sub>2</sub> SO <sub>4</sub> - charring.	Compares favorably to reference material

## Section 7. Standards of Identity, Purity, and Tests for D,L-Amygdalin.

### (1) Powder form:

- (a) Molecular formula: C<sub>20</sub>H<sub>27</sub>NO<sub>11</sub>;
- (b) Molecular weight: 457.4;
- (c) Description: White powder;
- (d) Solubility: (mg./ml.) Water 350; Methanol 100+; Chloroform 0.1;
- (e) Stability:

1. Solution: A solution of ten (10) mg. in one (1) ml. water shows no degradation as indicated by gas chromatography, after twenty-four (24) hours.

2. Bulk: A sample stored at sixty (60) degrees Celsius for thirty (30) days shows no degradation as indicated by gas chromatography.

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(f) Elemental composition:

Carbon	52.51
Hydrogen	5.95
Nitrogen	3.06
Oxygen	38.48

(g) Water: The compound shall not contain more than six (6) percent water, determined by Karl-Fischer;

(h) Infrared spectrum: The infrared spectrum conforms to reference material;

(i) Ultraviolet absorption: (H<sub>2</sub>O)

Alpha max	E
268 nm	206
262 nm	300
257 nm	280
252 nm	200

(j) Optical rotation:

$$[\alpha]_{\text{D}}^{21} = -52.0 (1, \text{H}_2\text{O})$$

(k) Nuclear magnetic resonance: (D<sub>2</sub>O)

Chemical Shift (δ)	Pattern	No. Protons	Assignment
3.2-5.2	m	14	Glucosyl protons
5.9	s	½	H - C - C = N (L-form)
6.1	s	½	H - C - C = N (D-form)
7.6	s	5	Phenyl protons

Internal Reference for Assay: Pyrocatechol, 6.9δ;

(l) Gas chromatography:

1. Column: three (3) percent OV-1 on 100/200 Chromosorb W-HP glass column, 6' x 2 mm;
2. Carrier gas: N<sub>2</sub>, forty (40) ml. per minute;
3. Oven temperature: 240 degrees to 275 degrees Celsius programmed at two (2) ml. per minute;
4. Sample: TMS-derivative (Prepare by dissolving one (1) mg. in five-tenths (0.5) ml. tri-sil with gentle heat.);
5. Detection: FID at 280 degrees Celsius;

(m) Thin layer chromatography:



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1. Adsorbent: SiO<sub>2</sub>-GF;
  2. Solvent system: n-BuOH/HOAc/H<sub>2</sub>O (12:3:1);
  3. Sample: 100Y , 200Y , (H<sub>2</sub>O);
  4. Detection: I<sub>2</sub>, UV, (NH<sub>4</sub>)<sub>2</sub>SO<sub>4</sub> - charring;
- (n) Purity: The compound consists of about 50:50 D,L-material. There shall not be more than three (3) percent total organic impurities. The compound shall not contain more than six (6) percent water;
- (o) Suggested identity tests:
1. Infrared spectrum;
  2. Ultraviolet absorption; or
  3. Nuclear magnetic resonance;
- (p) Suggested assay procedures:
1. Thin layer chromatography;
  2. Karl-Fischer determination; or
  3. Gas chromatography.

## (2) Sterile injectable form:

TEST	SPECIFICATION
Content uniformity	Ninety (90) to 110 percent of label
HPLC Method Column-300 mm. x 4 mm. I.D. Lichrosorb RP8 Mobile phase - 25% CH <sub>3</sub> OH in H <sub>2</sub> O Flow rate - 2 ml./min. Detector/sensitivity-uv at 254 nm./0.02 aufs.	The total of all uv absorbing impurities shall not exceed five (5) percent of this chromatogram.
Moisture - determine by Karl-Fischer	less than two (2) percent
Weight variation	Conforms to current USP
pH of reconstituted solution	4.0 to 8.0
Color of solution	Colorless
Clarity and completeness of solution	Conforms to current USP
Particulate matter	Conforms to current USP
USP sterility test	Sterile
USP pyrogen test	Nonpyrogenic at 600 mg./kg.

Thin layer chromatography Adsorbent: Silica gel GF Solvent system: n-BuOH/HOAc/H <sub>2</sub> O, 4/1/1 Sample applied: 400, 200Y (H <sub>2</sub> O) References: D,L-Amygdalin, 200Y (H <sub>2</sub> O) D,L-Amygdalinamide, 1, 2Y (H <sub>2</sub> O) D,L-Amygdalin acid, 1, 2Y (H <sub>2</sub> O) Detection: uv, I <sub>2</sub> , 30% H <sub>2</sub> SO <sub>4</sub> - charring.	Compares favorably to reference material
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#### **Section 8. Adulterated Amygdalin.**

Amygdalin shall be adulterated if:

- (1) It consists in whole or in part of a filthy, putrid, or decomposed substance;
- (2) Produced, prepared, packed, or held under unsanitary conditions where it may have been contaminated with filth or rendered injurious to health;
- (3) Its container is composed in whole or in part of a poisonous or deleterious substance which may render the contents injurious to health;
- (4) Its strength differs from, or its quality or purity falls below, the standard set forth in this administrative regulation. The determination of strength, quality, or purity shall be made in accordance with the tests or methods of assay in this administrative regulation;
- (5) Its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; or
- (6) It has been:
  - (a) Mixed or packed to reduce its quality or strength; or
  - (b) Substituted wholly or in part.

#### **Section 9. Misbranded Amygdalin.**

(1) Amygdalin shall be misbranded if:

- (a) Labeling is false or misleading in any particular;
- (b) In package form, unless it bears a label containing:
  1. Name and place of business of the manufacturer, and name and place of business of the packer or distributor, if other than manufacturer; and
  2. An accurate statement of the quantity of the contents in weight, measure, or numerical count; reasonable variations shall be permitted;
- (c) A word, statement, or other information required by 21 CFR 201.1 to 201.319 and this administrative regulation to appear on the label or labeling is not prominently placed with clarity (compared with other words, statements, designs, or devices, in the labeling) and in

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terms likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(d) The label does not state:

1. The common or usual name of Amygdalin;
2. Directions for use; and
3. Warnings against:
  - a. Use in pathological conditions where a danger to health exists;
  - b. Use by children where a danger to health exists; and
  - c. Unsafe dosage, methods, or duration of administration or application;

(e) It has been found by the cabinet to be apt to deteriorate, unless it is packaged in a manner to protect public health, and its label bears a statement of precautions;

(f) The container is made, formed, or filled to be misleading;

(g) It is an imitation of another substance;

(h) It is offered for sale under the name of another substance;

(i) It is dangerous to health if used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling;

(j) Intended for use by man unless, prior to dispensing, its label bears the statement "Caution: Kentucky law prohibits dispensing without prescription;" or

(k) The label, as originally packed, directs that it is to be dispensed or sold only on prescription, unless dispensed or sold on a prescription of an authorized practitioner, and its label, as dispensed, bears the name and place of business of the dispenser or seller, the serial number and date of the prescription, and the name of the licensed practitioner. Amygdalin prescriptions shall not be refilled.

(2) Amygdalin sold on a prescription of a practitioner shall be exempt from the requirements of this section if:

(a) The practitioner is licensed by law to administer Amygdalin; and

(b) Amygdalin bears a label containing:

1. The name and place of business of the seller;
2. The serial number and date of the prescription;
3. The name of the practitioner; and
4. The name of the patient for whom prescribed.

(3) It is not the intention of subsection (1)(b)1 of this section to require the name and place of business of the wholesaler to appear upon the label of the package.

### **Section 10. Inspections.**

The cabinet or its duly authorized agent shall have free access at all reasonable times to a factory, warehouse, or establishment in which Amygdalin is manufactured, processed, packed, or held for sale for the purpose of:

(1) Inspecting the factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling, to determine if any of the provisions of this administrative regulation are being violated.

(2) Securing samples or specimens of Amygdalin. It shall be the duty of the cabinet to make or cause to be made examinations of samples secured under the provisions of this section to determine if a provision of this administrative regulation is being violated.

(3) Examining or reproducing books, papers, documents, or other evidence pertaining to Amygdalin.

**Section 11. Detention or Quarantine of Amygdalin if Adulterated or Misbranded.**

(1) If a duly authorized agent of the cabinet finds, or has probable cause to believe, that any Amygdalin is adulterated or misbranded pursuant to this administrative regulation, the agent shall affix a tag or marking, giving notice that Amygdalin is, or is suspected of being, adulterated or misbranded and has been detained or quarantined. The tag or marking shall be a warning not to remove or dispose of Amygdalin until permission for removal or disposal is given by the agent or the district court. A person shall not remove or dispose of detained or quarantined Amygdalin without permission.

(2) If Amygdalin detained or quarantined under subsection (1) of this section has been found by the agent to be adulterated or misbranded, the agent shall petition the judge of the district court where the Amygdalin is detained or quarantined for an order for condemnation. Nothing in this section shall require the cabinet or its agent to go to court if destruction of the quarantined Amygdalin is accomplished by agreement made in writing with the owner. If the agent has found Amygdalin detained or quarantined is not adulterated or misbranded, the agent shall remove the tag or marking.

**Section 12. Revocation or Suspension of License.**

(1) The cabinet may suspend or revoke a license to manufacture Amygdalin for violation of a provision of this administrative regulation after proper notice and an opportunity for a due process hearing.

(2) All administrative hearings shall be conducted in accordance with 902 KAR 1:400.

**Section 13. Incorporation by Reference.**

(1) Form DCB-1, "Application for License to Manufacture Amygdalin", revised October 1993, is being incorporated by reference. This form may be inspected, copied or obtained at the Office of the Commissioner for Health Services, 275 East Main Street, Frankfort, Kentucky 40621, 8 a.m. until 4:30 p.m., Monday through Friday.

(2) 21 CFR 201.1 to 201.319, revised as of April 1, 1995, is being incorporated by reference. A copy may be inspected, copied or obtained at the Office of the Commissioner for Health Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. until 4:30 p.m. A copy may also be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

(3) 21 CFR 210.1 to 210.3, revised as of April 1, 1995, is being incorporated by reference. A copy may be inspected, copied or obtained at the Office of the Commissioner for Health Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. until 4:30 p.m. A copy may also be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

(4) 21 CFR 211.1 to 211.208, revised as of April 1, 1995, is being incorporated by reference. A copy may be inspected, copied or obtained at the Office of the Commissioner for Health Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. until 4:30 p.m. A copy may also be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. (23 Ky.R. 1300; eff. 9-18-96.)

## **902 KAR 55:105. Controlled substance prescription blanks.**

RELATES TO: KRS 218A.030-218A.140, 218A.204, 218A.170-218A.240, 218A.281, 218A.282, 218A.284, 218A.286, 218A.288

STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 211.090, 218A.204, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.204 requires the cabinet to promulgate administrative regulations that establish security requirements for a prescription blank used by a practitioner to write a prescription for a controlled substance. The purpose of this administrative regulation is to establish minimum requirements that will decrease the potential for forgery or alteration of a prescription or a prescription blank for a controlled substance.

### **Section 1. Definitions.**

- (1) "Logo" means a symbol utilized by an individual, a pharmacy, professional practice, professional association, or hospital.
- (2) "Security prescription blank" means a prescription blank that complies with the requirements of Section 3 of this administrative regulation.

### **Section 2. Security Prescription Blanks Required.**

- (1) Beginning January 1, 1999, a written prescription for a controlled substance shall be on a security prescription blank unless, pursuant to Section 7 of this administrative regulation, the cabinet has granted a waiver to the practitioner who wrote the prescription or to the pharmacy that dispenses it.
- (2) A practitioner who is licensed in Kentucky and in another state shall utilize a security prescription blank for writing a prescription for a controlled substance while practicing his profession within the Commonwealth unless, pursuant to Section 7 of this administrative regulation, the cabinet has granted a waiver to the practitioner or to the pharmacy that dispenses the controlled substance.

### **Section 3. Requirements of a Security Prescription Blank.**

- (1) A prescription for a controlled substance shall contain the following security features:
  - (a) A latent, repetitive "void" pattern screened at five (5) percent in pantone green shall be printed across the entire front of the prescription blank. If a prescription is photocopied, the word "void" shall appear in a pattern across the entire front of the prescription;
  - (b) A watermark shall be printed on the backside of the prescription blank so that it shall only be seen at a forty-five (45) degree angle. The watermark shall consist of the words "Kentucky Security Prescription", and appear horizontally in a step-and-repeated format in five (5) lines on the back of the prescription using twelve (12) point Helvetica bold type style;
  - (c) An opaque **R** symbol shall appear in the upper right-hand corner, one-eighth (1/8) of an inch from the top of the prescription blank and five-sixteenths (5/16) of an inch from the right side of the prescription blank. The symbol shall be three-fourths (3/4) of an inch in size and disappear if the prescription copy is lightened;
  - (d) Six (6) quantity check off boxes shall be printed on the form and the following quantities shall appear:
    1. ☐ 1–24;
    2. ☐ 25–49;

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3. ☐ 50-74;
  4. ☐ 75-100;
  5. ☐ 101-150;
  6. ☐ 151 and over;
- (e) A logo may appear on the prescription blank. The upper left one (1) inch square of the prescription blank shall be reserved for a logo;
- (f) The following statement shall be printed on the bottom of the prescription blank: "Prescription is void if more than one (1) prescription is written per blank";
- (g) Refill options shall appear below any logo on the left side of the prescription blank in the following order: Refill NR 1 2 3 4 5; and
- (h) A prescription blank shall be four and one-quarter (41/4) inches high and five and one-half (51/2) inches wide.
- (2) A prescription shall bear the preprinted, stamped, typed, or manually printed name, address and telephone number of the prescribing practitioner.
- (3) A prescription blank for a controlled substance shall not contain:
- (a) An advertisement on the front or the back of the prescription blank;
  - (b) The preprinted name of a controlled substance; or
  - (c) The written, typed, or rubber-stamped name of a controlled substance until the prescription blank is signed, dated and issued to a patient.
- (4) A prescription blank for a controlled substance shall provide space for the patient's name and address, the practitioner's signature and the practitioner's DEA registration number.

### **Section 4. Other Requirements.**

- (1) Only one (1) prescription shall be written per prescription blank.
- (2) A quantity check-off box that corresponds to the quantity prescribed shall be marked.
- (3) If a prescribed drug is a schedule III, IV or V controlled substance, a refill option shall be marked.
- (4) If a prescription for a schedule III, IV, or V controlled substance will be transmitted to a pharmacy by facsimile, the practitioner or the practitioner's agent shall, prior to transmission, write or stamp "FAXED" on the face of the original prescription along with the date and the person's initials.
- (5) If a pharmacist uses due diligence in ascertaining the validity of a prescription, a prescription for a schedule III, IV, or V controlled substance that is transmitted to a pharmacy by facsimile shall be exempt from the requirement of green ink in Section 3(1)(a) of this administrative regulation and the requirement of a watermark in Section 3(1)(b) of this administrative regulation.
- (6) If a prescription for a schedule III, IV or V controlled substance has been transmitted to a pharmacy by facsimile, the transmitting practitioner shall file the original prescription in the patient's record.

**Section 5. Exceptions.** A pharmacist shall not be required to use a security prescription blank to record an oral prescription or a transferred prescription for a Schedule III, IV, or V controlled substance.

**Section 6. Printers, Reproducers or Distributors of Security Prescription Blanks.** (1) A printer, reproducer or distributor of security prescription blanks shall require a written purchase

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order or request for security prescription blanks. A written purchase order or request shall remain on file for two (2) years.

(2) A purchase order or request shall be signed by:

- (a) A practitioner whose name shall be printed on the security prescription blanks; or
- (b) The chief medical official of a health care facility or pharmacist-in-charge of a pharmacy, if the security prescription blanks are requested on behalf of a practitioner who stamps, types or manually prints his name, address, telephone number and DEA number on the security prescription blank.

(3) The provisions of this section shall not apply to distributions between printers, reproducers, or distributors.

### **Section 7. Waiver of Security Prescription Blanks.**

(1) A practitioner or a pharmacy may apply in writing to the cabinet for a waiver from the requirement for security prescription blanks. A request for a waiver shall include:

- (a) A detailed statement of the security features provided by the system proposed by the applicant for the prevention of forgery or alteration of an original prescription; or
- (b) The format of the alternative prescription blank.

(2) The system or prescription blank proposed by the applicant shall provide a level of security equivalent to a security prescription blank.

(3) The cabinet shall grant or deny the application in writing within sixty (60) days after the request is received.

(4) When a waiver has been granted, the cabinet may suspend or revoke the waiver if the alternative system or alternative prescription blank does not provide security equivalent to a security prescription blank.

(5) Upon notification of denial, suspension, or revocation of the waiver of the requirement for a security prescription blank, the practitioner or pharmacy may request a hearing. The administrative hearing shall be conducted in accordance with 902 KAR 1:400. (25 Ky.R. 721; Am. 1074; 1366; eff. 12-16-98.)

## **902 KAR 55:110. Monitoring system for prescription controlled substances.**

RELATES TO: KRS 218A.010(9), 218A.202, 218A.240

STATUTORY AUTHORITY: KRS 194A.050, 218A.202(1), 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.202(1) directs the Cabinet for Health and Family Services to establish an electronic system for monitoring Schedule II, III, IV, and V controlled substances that are dispensed in the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy that has obtained authorization to operate from the Kentucky Board of Pharmacy. KRS 218A.250 requires the cabinet to promulgate administrative regulations pursuant to KRS Chapter 13A for carrying out the provisions of KRS Chapter 218A. This administrative regulation establishes criteria for reporting prescription data, providing reports to authorized persons, and a waiver for a dispenser who does not have an automated recordkeeping system.

### **Section 1. Definitions.**

(1) "Branch" means the Drug Enforcement and Professional Practices Branch in the Division of

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Audits and Investigations, Office of Inspector General, Cabinet for Health and Family Services.

- (2) "Cabinet personnel" means an individual who:
  - (a) 1. Is directly employed by the Cabinet for Health and Family Services; or
  - 2. Is employed by an agent or contractor of the cabinet;
  - (b) Has undergone KASPER training; and
  - (c) Has been approved to use the KASPER system.
- (3) "Dispenser" is defined by KRS 218A.010(9), and shall:
  - (a) Include a dispenser who has a DEA (Drug Enforcement Administration) number or is a pharmacist who owns or is employed by a facility that operates a pharmacy which has a DEA number; and
  - (b) Not include an individual licensed to practice veterinary medicine under KRS Chapter 321.
- (4) "Health facility" is defined by KRS 216B.015(13).
- (5) "KASPER" means Kentucky All-Schedule Prescription Electronic Reporting System.
- (6) "Patient identifier" means a patient's:
  - (a) Full name;
  - (b) Address, including zip code;
  - (c) Date of birth; and
  - (d) Social Security number or an alternative identification number established pursuant to Section 5 of this administrative regulation.
- (7) "Practitioner" is defined by KRS 218A.010(33).
- (8) "Report" means a compilation of data concerning a patient, dispenser, practitioner, or controlled substance.

### **Section 2. Data Reporting.**

- (1) A dispenser or a health facility that has a DEA number shall report all dispensed Schedule II, III, IV, or V controlled substances, except during the circumstances specified in KRS 218A.202(3)(a) and (b).
- (2) A dispenser of a Schedule II, III, IV, or V controlled substance shall transmit or provide the following data to the cabinet or the cabinet's agent:
  - (a) Patient identifier;
  - (b) National drug code of the drug dispensed;
  - (c) Metric quantity of the drug dispensed;
  - (d) Date of dispensing;
  - (e) Estimated day's supply dispensed;
  - (f) Drug Enforcement Administration registration number of the prescriber;
  - (g) Serial number assigned by the dispenser; and
  - (h) The Drug Enforcement Administration registration number of the dispenser.
- (3) (a) Prior to July 1, 2013, the data identified in subsection (2) of this section shall be transmitted



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within seven (7) days of the date of dispensing unless the cabinet grants an extension as provided in subsection (4) or (5) of this section.

(b) Prior to July 1, 2013, a dispenser that dispenses a controlled substance for the direct administration of the controlled substance to or for a patient in a licensed health facility shall not be required to transmit the data identified in subsection (2) of this section.

(c) Effective July 1, 2013, the data identified in subsection (2) of this section shall be transmitted no later than close of business on the business day immediately following the dispensing unless the cabinet grants an extension as provided in subsection (4) or (5) of this section.

(4)(a) An extension may be granted if:

1. The dispenser suffers a mechanical or electronic failure; or
2. The dispenser cannot meet the deadline established by subsection (3) of this section because of reasons beyond his or her control.

(b) A dispenser shall apply to the branch in writing for an extension listed in paragraph (a) of this subsection within twenty-four (24) hours of discovery of the circumstances necessitating the request or on the next date state offices are open for business, following the discovery. An application for an extension shall state the justification for the extension and the period of time for which the extension is necessary.

(5) An extension shall be granted to a dispenser if the cabinet or its agent is unable to receive electronic reports transmitted by the dispenser.

(6) Except as provided in subsection (8) of this section, the data shall be transmitted by:

- (a) An electronic device compatible with the receiving device of the cabinet or the cabinet's agent;
- (b) Secure File Transfer Protocol;
- (c) https protocol; or
- (d) Secure Virtual Private Network connection.

(7) The data shall be transmitted in the format established by the "ASAP Telecommunications Format for Controlled Substances", developed by the American Society for Automation in Pharmacy, Version 4.1, or a comparable format approved by the branch.

(8) A dispenser who does not have an automated recordkeeping system capable of producing an electronic report in the format established by "ASAP Telecommunications Format for Controlled Substances", shall report the data identified in subsection (2) of this section using an Internet accessible web portal designated by the cabinet.

**Section 3. Compliance.** A dispenser may presume that the patient identification information established in Section 5 of this administrative regulation and provided by the patient or the patient's agent is correct.

### **Section 4. Request for Report.**

(1) A written or electronic request shall be filed with the cabinet prior to the release of a report, except for a subpoena issued by a grand jury or an appropriate court order issued by a court of competent jurisdiction.

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(2) A request for a KASPER patient report shall be made electronically at [www.chfs.ky.gov/KASPER](http://www.chfs.ky.gov/KASPER).

(3) A request for a KASPER provider report made by a peace officer authorized to receive data under KRS 218A.202, or a designated representative of a board responsible for the licensure, regulation, or discipline of prescribing practitioners shall be made by written application on the "Request for KASPER Report (Law Enforcement and Licensure Boards)", Form DCB-15L.

(4) A medical examiner engaged in a death investigation pursuant to KRS 72.026 may query KASPER for a report on the decedent.

### **Section 5. Patient Identification Number.**

(1) A patient or the person obtaining the controlled substance on behalf of the patient shall disclose to the dispenser the patient's Social Security number for purposes of the dispenser's mandatory reporting to KASPER.

(2) If a patient is an adult who does not have a Social Security number, the patient's driver's license number shall be disclosed.

(3) If a patient is an adult who has not been assigned a Social Security number or a driver's license number, the number 000-00-0000 shall be used in the Social Security field.

(4) If a patient is a child who does not have a Social Security number or a driver's license number, the number "000-00-0000" shall be used in the Social Security field.

(5) If a patient is an animal, the number "000-00-0000" shall be used in the Social Security number field.

### **Section 6. KASPER Data and Trend Reports.**

Cabinet personnel shall be authorized access to the data obtained from the KASPER system and trend reports in accordance with KRS 218A.240(7)(a).

### **Section 7. Data Retention.**

Data shall be maintained in KASPER for a period of two (2) years plus the current year prior to its transfer to the State Archives and Records Commission.

### **Section 8. Error Resolution.**

(1) A patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic to whom a report has been disclosed under KRS 218A.202(8) or this administrative regulation may request that information contained in KASPER be corrected if the patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic believes that any information is inaccurate. The patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic shall:

(a) Contact the dispenser who reported the information required by Section 2(2) of this administrative regulation; and

(b) Request that the dispenser correct the information.

(2) If, upon receipt of a request from a patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic pursuant to subsection (1) of this section, the dispenser

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confirms that the information was reported in error, the dispenser shall:

- (a) Transmit corrected information to update the KASPER database within seven (7) days of the request for the correction; and
  - (b) Notify the patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic that the corrected information has been transmitted.
- (3) If a dispenser maintains that information regarding the dispensing of a controlled substance was correctly reported to KASPER and the KASPER system generates a report with inaccurate information, the dispenser shall contact the Drug Enforcement and Professional Practices Branch (DEPPB) to identify the source of an error in the KASPER report, and the cabinet shall correct the information in the KASPER database.
- (4) Upon correction of information in the KASPER database pursuant to subsection (3) of this section, cabinet staff shall notify the patient, patient's representative, practitioner, pharmacist, health facility, private practitioner's office or clinic within five (5) working days of the correction.

### **Section 9. Referrals to Licensing Boards.**

If the cabinet becomes aware that a prescriber or dispenser has failed to comply with the reporting requirements of KRS 218A.202 and this administrative regulation, the cabinet shall notify the licensing board or agency responsible for licensing the prescriber or dispenser.

### **Section 10. Disclosure of Data or Report.**

- (1) The cabinet shall only disclose data to the persons and entities authorized to receive that data under KRS 218A.202(6).
- (2) As a condition precedent to the disclosure of data or a report pursuant to KRS 218A.202(6)(f), a hospital or long-term care facility shall maintain, and provide upon request by the cabinet, a copy of the hospital or long-term care facility's policy for the management of KASPER data and reports which:
- (a) Describes the hospital or long-term care facility's internal procedures for educating the designated employee or employees on the:
    - 1. Proper use of the KASPER system;
    - 2. Prohibition on the improper use or intentional disclosure of KASPER data to unauthorized individuals; and
    - 3. Sanctions imposed for the improper use or intentional disclosure of KASPER data to unauthorized individuals, including criminal misdemeanor offenses; and
  - (b) Describes the hospital or long-term care facility's internal procedures for auditing the account, including:
    - 1. The manner in which an employee is added to or removed from access to the account if the employee ends employment or is no longer designated to query KASPER; and
    - 2. The actions taken if a designated employee with access to the employer's KASPER account intentionally misuses his or her privileges to KASPER data or a report, which shall include a report of the incident to the Office of Inspector General.
- (4)(a) An individual authorized to receive data under KRS 218A.202(6) shall not provide the data to any other entity except as provided in KRS 218A.202(8) and paragraph (b) of

this subsection.

(b) In addition to the purposes authorized under KRS 218A.202(8)(e), and pursuant to KRS 218A.205(2)(a) and (6), a practitioner or pharmacist who obtains KASPER data or a report under KRS 218A.202(6)(e)1. or who in good faith believes that any person, including a patient, has violated the law in attempting to obtain a prescription for a controlled substance, may report suspected improper or illegal use of a controlled substance to law enforcement or the appropriate licensing board.

(5) A hospital or long-term care facility shall maintain and adhere to the entity's internal policy regarding the management of KASPER data and reports.

#### **Section 11. Incorporation by Reference.**

(1) The following material is incorporated by reference:

(a) "ASAP Telecommunications Format for Controlled Substances", American Society for Automation in Pharmacy, Version 4.1, November 2009; and

(b) "Request for KASPER Report (Law Enforcement and Licensure Boards)", Form DCB-15L, 12/10.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Drug Enforcement and Professional Practices Branch, Office of the Inspector General, Cabinet for Health and Family Services, 275 E. Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

(25 Ky.R. 966; Am. 1367; eff. 12-16-1998; 32 Ky.R. 1927; 33 Ky.R. 120; eff. 7-24-2006; 34 Ky.R. 2609; 35 Ky.R. 283; eff. 9-5-2008; 2615; eff. 7-31-2009; 39 Ky.R. 629; 1218; 1413; 2033; eff. 3-4-2013.)

### **902 KAR 55:115. Drug possession by hospice or home health agency.**

RELATES TO: KRS 217.005-217.215, 217.992

STATUTORY AUTHORITY: KRS 194A.050, 211.090, 217.125, 315.300

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.300 authorizes the Cabinet for Health Services to promulgate administrative regulations that implement the possession of certain drugs by a hospice or home health agency. The purpose of this administrative regulation is to establish criteria that a pharmacy, hospice or home health agency must meet in order to insure that drugs belonging to a pharmacy, that are stored in a hospice or home health agency, are safe and effective for administration to patients.

#### **Section 1. Authorized Employees.**

A pharmacy may place a legend drug listed in KRS 315.300 with an authorized employee of a hospice or a home health agency if the pharmacy maintains a record of the license that authorizes the employee to administer legend drugs.

**Section 2. Written Agreement.**

Each party to a written agreement between a pharmacy and a home health agency or a pharmacy and a hospice shall maintain a copy of the written agreement.

**Section 3. Protocol.**

- (1) A protocol required by KRS 315.300 may be included in the written agreement or may be a separate document.
- (2) If the protocol is a separate document, a copy shall be maintained by the pharmacy and by the hospice or home health agency.
- (3) The protocol shall be reviewed not less than annually and modified if necessary.

**Section 4. Records.**

- (1) The pharmacy record of a drug placed with authorized employees of a hospice or home health agency shall be retained for five (5) years.
  - (2) The record of a drug administered by authorized employees of a hospice or home health agency shall be retained by the pharmacy for five (5) years.
- (25 Ky.R. 723; Am. 1369; eff. 12-16-98.)